K012913

Bard Peripheral Technologies
C.R. Bard, Inc.
13183 Harland Dr., N.E.
Covington, GA 30014

SEP 2 8 2001

BARD

510(k) SUMMARY OF
SAFETY AND EFFECTIVENES INFORMATION

A. Submitter Information:

Submitter's Name: C.R. Bard, Inc., Peripheral Technologies Division
Submitter's Address: 13183 Harland Drive, Covington, GA 30014
Contact Person: Carol Vierling
Contact Person's Telephone Number: (770) 385-2347
Contact Person's FAX Number: (770) 385-2340
Date of Preparation: August 30, 2001

B. Device Name:

Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter

C. Predicate Devices:

Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter
Bard® Opti-Plast™ PTA Catheter
Boston Scientific Symmetry™ Balloon Dilatation Catheter

D. Device Description:

The Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter is a dual lumen catheter with a balloon mounted on its distal tip. One lumen accommodates the insertion guidewire and the second provides a channel for inflation/deflation of the balloon. There are two radiopaque marker bands placed beneath the balloon to indicate its position within the vasculature.

E. Intended Use:

The Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, femoral and peroneal vessels. This catheter is not for use in coronary arteries.

F. Technological Characteristics Summary:

The Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter has a 3.5 Fr shaft and is available in lengths of 100 and 120 cm. Various balloon diameters and lengths are available.

G. Performance Data:

The design, materials and manufacturing process for the predicate and the modified device are the same. Bench testing shows that the modified catheter is substantially equivalent to the predicate Ultraverse Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 8 2001

C.R. Bard, Inc.
c/o Ms. Carol Vierling
13183 Harland Dr, NE
Covington, GA 30014

Re: K012913
Trade Name: Bard Ultraverse Small Vessel PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 30, 2001
Received: August 30, 2001

Dear Ms. Vierling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

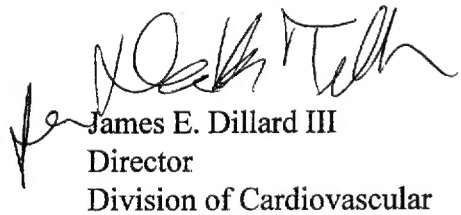
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 5

Indications for Use Statement

Device Name	Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter
Indications for Use	The Bard® Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the renal, tibial, popliteal, femoral and peroneal vessels. This catheter is not for use in coronary arteries.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012913

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109